

III. Remarks

A. Introduction

Reconsideration and allowance of the present application are respectfully requested.

Claims 64, 129-138, 140-142, and 144-155 are pending in the present application. Claim 64 is independent. Claims 135-138, 141, 142, and 144-147 have been withdrawn from further consideration as directed to a non-elected species. Claims 138 and 143 have been cancelled. Claims 64, 129, 130 and 140 are amended. Claims 153-155 have been added. No new matter has been introduced by way of such amendments.

B. Election/Restrictions

In response to the Restriction Requirement mailed on August 22, 2007, Applicant elected Group IV, without traverse. The Examiner indicated that the Applicant failed to address the election of species requirement. Applicant respectfully disagrees. The Restriction Requirement stated that “in the event the applicant elects to proceed with *Inventions I, II, III or V*” that an election of one surfactant, opioid, and filler is required. *See* Restriction Requirement, pages 5-7; emphasis added. The Restriction Requirement did **not** require an election of species in the event the Applicant elected Invention IV. Subsequently, the Examiner added the election requirement for Invention IV (*see* communication dated October 11, 2007) and Applicant elected docustate sodium as the surfactant species, morphine as the opioid species, and corn starch as the filler species. In response, the Examiner indicated that claims 135-138, 141, 142 and 144-147 are withdrawn from consideration as being drawn to non-elected subject matter. Claims 140, 148 and 149 correspond to the elected surfactant. Claims 154 and 155 correspond to the elected opioid. Claim 153 corresponds to the elected filler.

C. Priority

The Examiner stated that the earlier filed applications “fail to provide support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application.” *See* Office Action, page 3. Applicant respectfully disagrees based on the claims as currently amended. The present application is a continuation of U.S. Application No. 10/349,431, filed on January 22, 2003 (now U.S. Patent No. 6,713,470), and thus contains the same disclosure as the present application. U.S. Application No. 10/349,431 also claims priority to UK 0201367.0, filed on January 22, 2002. Applicant notes that the Office Action incorrectly referenced EP 0201367.0. A

certified copy of UK 0201367.0 is submitted herein. UK 0201367.0 supports the claims as amended, namely on page 5, lines 4-7 and page 6, line 27 to page 7, line 5. Therefore, Applicant is entitled to the earlier priority date of January 22, 2002 and a claim of priority under 35 U.S.C. § 119(a)-(d) can be maintained.

D. Information Disclosure Statement

Applicant filed an information disclosure statement that complies with 37 C.F.R. § 1.98 on February 28, 2008. Acknowledgement of that information disclosure statement would be appreciated.

E. Applicant Data Sheet

Applicant thanks the Examiner for identifying the typographically error in the Application Data Sheet (ADS). The correct information was provided in the preliminary amendment filed on January 7, 2004. A supplemental ADS is submitted herein to address this typographically error.

F. Objections to the Specification

The Office Action objected to the abstract of the disclosure. Applicant has amended the abstract to address the objections raised in the Office Action.

Applicant thanks the Examiner for the information provided on the suggested format of an application. Contrary to the specific objection raised by the Examiner, Applicant has provided a cross-reference to priority in the Preliminary Amendment filed on January 7, 2004.

The Office Action objected to the title for not being descriptive. Applicant has amended the title to address the objections raised in the Office Action.

G. Claim Rejections under 35 U.S.C. § 112

Claims 64, 129-134 and 148-152 stand rejected under 35 U.S.C. § 112, first paragraph, for failing to comply with the written description requirement. This rejection is rendered moot by the amendments to Claim 64.

Claim 64 stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. This rejection is rendered moot by the amendments to claim 64. Applicant notes that the objection to “the surfactant” in line 7 of amended claim 64 is improper, because antecedent basis for this limitation is found in lines 5-6 of amended Claim 64, namely “a pharmaceutically acceptable surfactant.”

Claims 64, 129-134 and 148-152 stand rejected under 35 U.S.C. § 112, first paragraph, because the specification does not reasonably provide enablement. This rejection is rendered moot by the amendments to Claim 64.

H. New Matter Rejection under 35 U.S.C. § 132(a)

The Office Action objects to the Amendment filed on September 19, 2007, as introducing new matter under 35 U.S.C. § 132(a). This rejection is rendered moot by the amendments to claim 64.

I. The Rejection of Claims 64, 129-130, 139-140, 143 and 148-152 under 35 U.S.C. § 103(a) Over Iversen and Further in View of RPS is *Prima Facie* Deficient and Should Be Withdrawn

Claims 64, 129-130, 139-140, 143 and 148-152 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over WO9918967 to Iversen, *et al.* (“Iversen”) in view of “Remington’s Pharmaceutical Sciences,” Mack Publishing Co., 1975, 15th ed., pp. 295-296, and 1266 (“RPS”). Based on the above amendments and following remarks, without addressing the alleged motivation to combine, this rejection should be withdrawn because the combination of Iversen and RPS is *prima facie* deficient due to the failure of the alleged combination to teach every claim feature.

It is well settled that the Patent Office bears the burden of establishing a *prima facie* case of obviousness under 35 U.S.C. § 103. *See In re Deuel*, 51 F.3d 1552, 1557 (Fed. Cir. 1995). To establish a *prima facie* case of obviousness, the Patent Office must first show that the prior art suggested to those of ordinary skill in the art that they should make the claimed device or composition. Second, it must show that the prior art would have provided one of ordinary skill in the art with a reasonable expectation of success. Both the suggestion and the reasonable expectation of success must be adequately founded in the prior art and not in an applicant’s disclosure. Third, the Patent Office must show that the prior art teaches or suggests every claim limitation. *See Manual of Patent Examination and Procedure* (MPEP) § 2143; *In re Vaeck*, 20 U.S.P.Q.2d 1438, 1442 (Fed. Cir. 1991).

Independent Claim 64, as amended, recites “monophasic pharmaceutical composition.” The Office Action does not state that Iversen teaches a monophasic pharmaceutical composition, but rather states that “the CCK antagonist would need to be formulated with a satisfactory carrier.” *See* Office Action, page 17. The only carrier that Iversen teaches is a biphasic carrier. *See* Iversen, page 2, line 25. RPS is only cited for teaching specific pharmaceutical excipients, such as surfactants and fillers, and cannot remedy the deficiency of Iversen. Therefore, the rejection of Claim 64 is *prima facie* deficient because the Office Action failed to provide a single or combination of references that teaches every claim element and the rejection should be withdrawn.

The dependent claims, including the newly added dependent claims, contain all the limitations of independent Claim 64 from which they depend and thus are patentable over the cited reference for at least the same reasons as independent Claim 64.

J. Conclusion

In view of the above remarks, it is believed that this application is in condition for allowance, and a Notice thereof is respectfully requested.

Applicant’s undersigned attorney may be reached in our Washington, D.C. office by telephone at (202) 625-3536. All correspondence should continue to be directed to our below-listed address.

Respectfully submitted,

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